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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,838	12/08/2005	Eduardo N. Mitrani	28888	9337
7590 04/29/2008				
Martin Moynihan Anthony Castorina Suite 207 2001 Jefferson Davis Highway Arlington, VA 22202			EXAMINER KIM, TAEYOON	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 04/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,838

Applicant(s)

MITRANI ET AL.

Examiner

Taeyoon Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 174-208 is/are pending in the application.
4a) Of the above claim(s) 174-186 and 190-206 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 187-189 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 09 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/11/2008
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claims 174-206 and 213-218 are pending.

Response to Amendment

Applicant's amendment and response filed on 1/9/2008 has been received and entered into the case.

Claims 207-212 have been canceled, claims 174-186, 190-206 and 213-218 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 187-189 have been considered on the merits. All arguments have been fully considered.

The drawings were received on 1/9/2008. These drawings are accepted.

The claim objection has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §112 has been withdrawn due to the amendment.

In the response to the claim rejection under 35 U.S.C. §103 based on Mitrani in the previous office action, applicant argued that the reference does not describe or suggest a functionally integrated apparatus which can be used for a one step tissue harvesting and processing. This argument is not persuasive since a person of ordinary skill in the art would recognize that the use of tools convenient and efficient for obtaining tissue biopsy is desirable in the art, and there are numerous tools capable of scraping tissues and cutting tools for such tissue biopsy. Therefore, a person of ordinary skill in the art would use such tools available in the art to obtain tissues fragmented for microorgan culture. It is clearly disclosed by Mitrani that the tissue (e.g. fresh skin) can be prepared into final tissue segments by using a tissue chopper or other suitable

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cutting means (see Example 1). Although Mitrani does not particularly teach such tools (scrapers and cutters), these are well known in the art to be used for scraping tissues and cutting such tissues into smaller fragments. For example, a tissue scraper for tissue biopsy is taught by McMillan (US 4,951,684), and the use of cutter on a cutting chamber is extremely well known in the art for the chopping tissues for further use (e.g. primary culture).

Furthermore, the use of a scraper operably coupled with the cutting chamber would be obvious modification to a person of ordinary skill in the art because it is a mere choice of engineering the apparatus.

M.P.E.P. §2144.04 states "*In re* Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (A claim to a fluid transporting vehicle was rejected as obvious over a prior art reference which differed from the prior art in claiming a brake drum integral with a clamping means, whereas the brake disc and clamp of the prior art comprise several parts rigidly secured together as a single unit. The court affirmed the rejection holding, among other reasons, "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice."); but see *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) (Claims were directed to a vibratory testing machine (a hard-bearing wheel balancer) comprising a holding structure, a base structure, and a supporting means which form "a single integral and gaplessly continuous piece." Nortron argued that the invention is just making integral what had been made in four bolted pieces. The court found this argument unpersuasive and held that the claims were patentable because the prior art

perceived a need for mechanisms to dampen resonance, whereas the inventor eliminated the need for dampening via the one-piece gapless support structure, showing insight that was contrary to the understandings and expectations of the art.).”

Furthermore, applicant asserted that the example of Mitrani would not benefit from the “automation” of the current application. Applicant is reminded that there is no limitation in the current invention claiming “automation” or “automated process” of using an apparatus having a tissue scraper and a cutting chamber operably coupled. As applicant acknowledged in the response, the limitation of “operably coupled” can be interpreted as functionally coupled but not necessarily physical coupling. Thus, the use of scraper and cutter to prepare micro-organs or tissue biopsy samples for culture as taught by Mitrani would meet the limitations of “operably coupled”.

Even though the limitation “operably coupled” is considered to be an “automation” process of scraping and cutting of tissue biopsy, this is not persuasive since “automation” is also considered to be obvious as supported by the legal precedent as a source of supportive rationale.

M.P.E.P. §2144.04 states “*In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (Appellant argued that claims to a permanent mold casting apparatus for molding trunk pistons were allowable over the prior art because the claimed invention combined “old permanent-mold structures together with a timer and solenoid which automatically actuates the known pressure valve system to release the inner core after a predetermined time has elapsed.” The court held that broadly providing an automatic

or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.).”

Therefore, the holding of 35 U.S.C. §103 to claims 187-189 based on Mitrani is a must.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/009,520, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The limitations of “a tissue scraper” and “a cutting chamber” of the current invention do not have proper support from the '520 application, and therefore, the benefit of the earlier filed application would not be granted to the filing date of the '520 application. The earliest filing date of the current application is considered to be the filing date of the 10/193,136 application, which is 7/12/2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 187-189 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitrani (US 5,888,720) in light of McMillan (US 4,951,684).

Claims 187-189 are drawn to a method of generating micro-organs from a tissue biopsy comprising providing an apparatus having a tissue scraper for obtaining a tissue biopsy and a cutting chamber for cutting the tissue biopsy into a plurality of micro-organs, and using the apparatus to generate micro-organs; a limitation to the tissue being a skin; a limitation to the method further comprising testing a viability of the micro-organs using a viability testing chamber.

Mitrani teaches a method of generating micro-organs from skin biopsy by cutting the skin biopsy into multiple fragments with a suitable cutting means, forming micro-organs (see Fig. 1 and Example 1).

Although Mitrani does not particularly disclose a step of scraping tissue biopsy

prior to cutting step, since the method step of "cleaning fresh skin to remove underlying fat tissue and cut into 0.4x5 cm flaps, which are then transversely sectioned, using a tissue chopper or other suitable cutting means" as disclosed in Example 1 of Mitrani would be carried out a tissue scraper and a tissue cutter, it would have been obvious to a person of ordinary skill in the art to use a tissue scraper to collect 0.4x5 cm tissue flaps of Mitrani, and cut the flaps transversely with a tissue cutter as disclosed by Mitrani. One scraper suitable for such purpose is disclosed by McMillan. McMillan teaches a tissue scraper to collect biological material including skin (abstract and col. 4, lines 3-5).

The Supreme Court recently states in *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

With the limitation of "testing a viability of the micro-organ using a viability testing chamber operably coupled to the cutting chamber", this limitation is met by Mitrani disclosing "cell viability test" determining DNA synthesis (col. 12, claim 2).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Taeyoon Kim
AU-1651